

**From:** McMahon, Carrie  
**To:** [Yingling, Gary L.](#) [REDACTED]  
**Cc:** [Vaughn, Jessica L.](#) [REDACTED] [Merker, Robert I.](#)  
**Subject:** Impossible Foods: draft GRAS notice, FDA's observations  
**Date:** Tuesday, September 05, 2017 5:11:00 PM  
**Attachments:** [image001.png](#)

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Dear Mr. Yingling,

**REGARDING: Impossible Foods' draft GRAS notice**

Our technical review staff have considered the information in Impossible Foods' draft GRAS notice for its protein preparation from *Pichia pastoris* expressing soy leghemoglobin. At this time, we do not have additional technical observations to relay, but would like to remind you of those discussed during our meeting on August 18, 2017. These include:

- an observation by Dr. Choudhuri regarding the text on page 38 (Section 6.4.4 Sequence Homology). Dr. Choudhuri provided Dr. Fraser with a copy of the page, on which he highlighted the text in question.
- observations by FDA attendees regarding the clarity of the text describing the subject of the GRAS conclusion (i.e., the protein preparation). Several attendees pointed out that the text and figures (Table 1) describing the complete composition (primarily water, with soy leghemoglobin and *P. pastoris* proteins) could be clearer. For example, Table 1 notes the soy leghemoglobin level but makes no mention of the *P. pastoris* protein level, which is not insignificant (approximately 1/3 of total protein).
- a request by Dr. Srinivasan that Impossible Foods review its notice to ensure that references to the soy leghemoglobin protein, the protein preparation, and protein preparations adapted for use in the toxicity studies are unambiguous.

We note from a regulatory perspective that there is no mention in the draft GRAS notice of the color of the protein preparation or of the effect its color could have on the appearance of the intended food products. While the notice explains that the purpose of the characterizing component of the protein preparation (i.e., soy leghemoglobin) is to create a flavor impact on ground beef analogue products, Impossible Foods' website explains that "heme" also contributes to the characteristic color of meat and shows pictures of red and brown ground beef analogue products. Unlike the food additive definition in the Federal Food, Drug, and Cosmetic Act, the color additive definition does not have a GRAS exemption. Please explain your legal rationale for concluding that the protein preparation, containing soy leghemoglobin, is not a color additive under the FD&C Act.

Please do not hesitate to contact me if you have any questions about FDA's observations.

Regards,  
**Carrie McMahon, Ph.D.**  
Consumer Safety Officer

Center for Food Safety and Applied Nutrition  
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U.S. Food and Drug Administration  
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